

Welcome to the Division of Disease Prevention's
HBV and HCV
Website Referral, Treatment Explanation, and
Patient Assistance Programs.

HBV Website Referral, Treatment Explanation and Patient Assistance Programs

HBV Website Referral

Clinical Trials:

Center Watch, Clinical Trials Listing Service:

<http://www.centerwatch.com/patient/studies/cat79.html>

For information on clinical trials for hepatitis.

www.clinicaltrials.gov ClinicalTrials.gov provides regularly updated information about federally and privately supported clinical research in human volunteers, including a trial's purpose, who may participate, locations, and phone numbers for more details.

General HBV:

[Hepatitis B Foundation](http://www.hepb.org) (www.hepb.org)

[CDC Hepatitis Branch](http://www.cdc.gov/ncidod/diseases/hepatitis/) (http://www.cdc.gov/ncidod/diseases/hepatitis/)

Asian American Health (<http://asianamericanhealth.nlm.nih.gov/>)

American Liver Foundation (<http://www.liverfoundation.org/>)

Ahschc.org - Asian Health Services provides patient education, screening and disease management for the immigrant and refugee Asian community.

Apiahf.org - Asian and Pacific Islander Health Forum is a national advocacy organization dedicated to health policy, patient education and medical research efforts for the Asian American and Pacific Islander communities.

Hepfi.org - Hepatitis Foundation International initiates a wide range of programs to educate the public, patients, and medical professionals about prevention, diagnosis and treatment of viral hepatitis.

Hepprograms.org - This Web site provides information on programs across the United States that work to prevent hepatitis A, B and/or C in people who are at risk for infection.

HIVandHepatitis.com - This online publication provides medical and patient information about treatment for HIV/AIDS, chronic hepatitis B and hepatitis C, and co-infection with HIV/HCV and HIV/HBV.

Immunize.org - The Immunization Action Coalition is a source of childhood, adolescent and adult immunization information and hepatitis B educational materials. The Hepatitis B Coalition, a program of the Immunization Action Coalition, provides hepatitis B screening, education and treatment programs for people who are chronically infected with hepatitis B.

Asian Liver Center at Stanford University (<http://livercancer.stanford.edu/>) - The Asian Liver Center at Stanford University is a non-profit organization founded to address the high incidence of hepatitis B and liver cancer in Asians and Asian-Americans, and is the home of the "Jade Ribbon Campaign".

Vhpb.org - The objective of the Viral Hepatitis Prevention Board (VHPB) is to contribute to the control and prevention of viral hepatitis.

Hepatitis Foundation International - Sponsors support groups across the country for hepatitis sufferers and their families. Visit <http://www.hepfi.org/> for information about support groups in your area.

HBV Treatment Explanation and Patient Assistance Programs

There is no cure for chronic HBV. The purpose of treatment is the following:

- **To Reduce Viral Load and Achieve a Sustained Virologic Response (SVR);**
- **To Normalize the ALT Levels;**
 - **To Seroconvert the Hepatitis B e Antigen (HBeAg) to HBeAb**
 - **To Significantly Reduce Liver Inflammation and Necrosis and Thereby Avoid/Reverse Fibrosis, Cirrhosis, and Liver Cancer**

Prior to treatment the gastroenterologist may want to do the following tests:

- **Liver Biopsy**
- **HBV Genotype**
- **Ultrasound**
- **HBV Quantitative PCR**

Below is a list of those HBV treatments currently approved by the FDA:



About Hepsera ®

Hepsera® is administered as an oral 10 mg tablet. Talk to your doctor to discuss how much Hepsera to take and how often you need to take it.

Important Tips:

- You may take Hepsera with or without food.
- Take Hepsera exactly as instructed by your doctor.
- If you forget to take Hepsera, take it as soon as you remember that day. Do not take more than one dose of Hepsera in a day and do not take two doses at the same time
- It is very important that you do not stop taking Hepsera unless instructed to do so by your doctor. Some patients who stop taking Hepsera get a very serious hepatitis. It is unknown how long you should take Hepsera. Your doctor will decide when it is best for you to stop treatment with Hepsera.

Gilead Patient Assistance Program

Gilead demonstrates its compassion and commitment to patients by providing expanded access to investigational therapeutics when possible.

To find out if you are eligible for this patient assistance program, please call:

1-800-445-3235 between 8:00 a.m. and 5:00 p.m. PT.



About Epivir-HBV ®

Lamivudine is an antiviral agent that blocks the multiplication of hepatitis B virus.

The dose regimen is usually 100mg (one tablet) once a day. The duration of treatment has not been defined. Currently, it seems that a minimum of 1 year treatment is necessary. Treatment may be discontinued in patients who have cleared hepatitis B e antigen and hepatitis B viral DNA. Patients with kidney failure may need reduced dosing while patients with combined HIV and hepatitis B infection require a higher dose.

Adults with chronic hepatitis B - hepatitis B surface antigen positive for at least 6 months, markers of active infection - hepatitis B DNA positive and evidence of liver disease - abnormal liver enzymes.

Approximately 15-30% of patients develop resistant hepatitis B virus mutations (changes in the virus gene) after 1 year of treatment. The risks of resistance increase with longer durations of treatment. Patients with resistance may develop breakthrough infection - reappearance of hepatitis B virus DNA and increased liver enzymes.

GlaxoSmithKline Bridges To Access Program

GlaxoSmithKline patient assistance programs provided \$372.5 million (WAC value) worth of medicines and enrolled over 475,000 patients during 2004.

GlaxoSmithKline believes that timely access to prescription medicines is an essential part of cost-effective and comprehensive medical care. As a leader in pharmaceutical research, we are committed to helping patients gain access to the breakthrough medicines we discover.

As part of that commitment, GlaxoSmithKline has established Bridges to Access which provides out-patient medications to eligible low-income patients residing in the United States who do not have prescription drug benefits.

Please browse our site for more information on the program and its benefits including specific information about our:

- Eligibility criteria
- Enrollment forms
- Telephone enrollment process
- Mail order distribution system for obtaining refill medicines
- Enhanced telephone menu options that allow advocates to request enrollment forms, order prescription refills, add or change a prescription, and check patient eligibility status 24 hours a day, seven days a week
- Annual re-enrollment process

Contact Information

Enrollment form and other patient specific-questions: **1-866-728-4368**

All other questions: **1-888-825-5249**

Monday - Friday, 8am - 8pm Eastern Time.



Bristol-Myers Squibb Company



About Baraclude ®

BARACLUDGE is an oral antiviral therapy specifically designed to block the replication of hepatitis B virus (HBV) in the body by interfering with the virus's ability to infect cells. The drug will be available in the United States as early as April 8, 2005.

BARACLUDGE is indicated for the treatment of chronic hepatitis B infection in adults with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease.

BARACLUDGE is a nucleoside analogue with a recommended dosage of a single 0.5-milligram tablet once-daily for chronic hepatitis B patients beginning treatment for the first time (nucleoside-naïve patients), and a single 1- milligram tablet once-daily for patients experiencing resistance to lamivudine (lamivudine-refractory patients).

Bristol-Myers Squibb Access Program for Oncology/Virology

Patients must have no insurance coverage for prescription needed. The patient must be treated out-patient and treated on an ongoing process. Patients must also meet financial guidelines. Call between 8-5pm CST.

1-800-272-4878



About Intron A ®

Natural interferon is a protein produced by the body's cells in response to viral infections. There are three types: alfa, beta and gamma. Commercially-produced (genetically-engineered) interferon alfa mimics the activity of naturally-occurring interferon alfa produced by the body, although the mechanism of action of the drug is not well understood.

Intron A is injected subcutaneously (just under the skin) or intramuscularly. The recommended dose of Intron A for HBV treatment is 5 million International Units (IU) daily for 16 weeks.

Schering-Plough Patient Assistance Program

Schering-Plough is committed to improving the health and well-being of people throughout the world. In fulfilling that commitment, we are developing new treatments and programs that assist patients in achieving their best possible therapeutic outcomes. In the United States, an important part of this effort involves helping patients through our patient assistance and patient support programs.

Schering-Plough believes that the pharmaceutical industry needs to address the challenges facing low-income, chronically ill, underinsured and/or other uninsured people who cannot access the prescription medicines they need to improve their health. We support efforts to increase access, and are committed to assisting patients in need to obtain treatment. We continuously evaluate our patient assistance programs for their ability to do the most good for the most people. We intend to maintain and, to the extent financially prudent, expand our programs.

Informal patient assistance programs have been in place at Schering-Plough since the early 1980s. In 2004, these programs provided some 90,000 patients with more than \$120 million worth of free Schering-Plough products. Today, patients can apply for assistance through two programs:

Commitment to Care (1-800-521-7157), which covers our cancer and hepatitis drugs; and
SP-Cares (1-800-656-9485), which includes our other prescription drugs.

HCV Website Referral, Treatment Explanation and Patient Assistance Programs

HCV Website Referral

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General HCV:

All About Hepatitis C: www.all-about-hepatitisc.com

This website, sponsored by Schering-Plough, is designed to help individuals learn more about hepatitis C, including its causes, transmission, consequences, prevention, and diagnosis and treatment. The website is intended for those who want to learn more about hepatitis C, think they might be at risk, or have been diagnosed with hepatitis C and are wondering about the challenges facing them.

American Liver Foundation (ALF): www.liverfoundation.org

ALF is a national, voluntary nonprofit health agency dedicated to preventing, treating, and curing hepatitis and all liver diseases through research, education, and support groups.

HCV Anonymous: www.hcvanonymous.com

HCV Anonymous Positive Attitudes is a 12 step program designed to bring HCV patients, family members, friends, and health care professionals together to help provide support to everyone affected by HCV. This site provides many links to other websites, and also is a confidential online support group for members to discuss therapy, side effects, costs, insurance issues, employment, and more.

Hepatitis Foundation International (HFI): www.hepfi.org

HFI focuses on bringing viral hepatitis under control through education programs and materials, informing health professionals, and educating patients and the public about new diagnostic and treatment methods to improve patient care. Website includes support group information.

Hepatitis C Advocacy: www.hepcadvocacy.org

This website provides up-to-date information on hepatitis C, HIV, and HCV/HIV co-infection as it relates to federal and state lobbying efforts and HIV and HCV public policies and funding programs.

Hepatitis C Society of Canada: www.hepatitiscsociety.com

The Hepatitis C Society of Canada is a national voluntary health organization whose mission is to fight hepatitis C through prevention, early diagnosis, support, appropriate treatment, and comfort.

Hepatitis C Support Project HCV Advocate: www.hcvadvocate.org

This website has information on hepatitis C and B for the general public and offers free information packets. Website includes hepatitis C support group information.

Hep C Connection: www.hepc-connection.org

Information to help hepatitis C-challenged individuals and their families.

HIV&Hepatitis.com: www.HIVandHepatitis.com

This online publication provides news and research information about treatment and experimental vaccine options for hepatitis disease and HIV infection.

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- **To Significantly Reduce Liver Inflammation and Necrosis and Thereby Avoid/Reverse Fibrosis, Cirrhosis, and Liver Cancer**

Prior to treatment the gastroenterologist may want to do the following tests:

- **Liver Biopsy**
- **HCV Genotype**
- **Ultrasound**
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Below is a list of HCV treatments currently approved by the FDA:



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Natural interferon is a protein produced by the body's cells in response to viral infections. There are three types: alfa, beta and gamma. Commercially-produced (genetically-engineered) interferon alfa mimics the activity of naturally-occurring interferon alfa produced by the body, although the mechanism of action of the drug is not well understood.

Intron A is injected subcutaneously (just under the skin) or intramuscularly. The recommended dose of Intron A for HCV treatment is 3 million International Units (IU) three times weekly for 18-24 months in patients who respond. In patients who do not respond by week 16, consideration should be given to the discontinuation of therapy. At that point such patients rarely will achieve a sustained response with further treatment.



About Peg-Intron ®

Peg-Intron is a preferred choice of therapy over Intron A. Peg-Intron is usually given as a combination with Rebetol (see below.)

PEG-INTRON® is the first once-weekly pegylated interferon approved by the Food and Drug Administration (FDA) for hepatitis C in previously untreated patients with compensated liver disease and who are at least 18 years of age.

With PEG-INTRON®, a substance called polyethylene glycol (PEG) is attached to interferon so that it stays in your body longer before it is broken down and eliminated. This process is called pegylation. The main benefit of pegylation is that you only have to take one shot per week, instead of three, and there is a slightly better viral response.

About Rebetol ®

REBETOL® is an antiviral drug (ie, a drug that fights against viruses). REBETOL® alone is not effective for the treatment of chronic hepatitis C. REBETOL® is used in combination with PEG-INTRON® to treat chronic hepatitis C.

Schering-Plough Patient Assistance Program

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About Pegasys®

PEGASYS is a preferred choice of therapy over Intron A. It is usually given as a combination with Copegus (see below.)

PEGASYS is a treatment option for hepatitis C patients. It is a pegylated interferon that uses technology to better meet patients' needs. PEGASYS is the only pegylated interferon available as a ready-to-use solution. And no matter what your weight is, patients usually

take the same dose of PEGASYS. Pegylation also allows PEGASYS to be a once-weekly medication.

More than 20,000 hepatitis C patients were treated in PEGASYS clinical trials all over the world, and ongoing trials for more uses of PEGASYS continue today. At Roche, we're making a genuine commitment to treating people with hepatitis C.

PEGASYS can be prescribed along with a drug called COPEGUS. The benefit of combination therapy is that more patients tend to respond to combination therapy than they would to PEGASYS alone.

About Copegus®

COPEGUS is an antiviral medication that is used in combination with PEGASYS to help fight the hepatitis C virus. Although ribavirin cannot fight hepatitis C on its own, studies have shown that it does help alpha interferon work better.

With PEGASYS and COPEGUS combination therapy, the hepatitis C virus can be decreased to a level so low that it cannot be measured by blood tests. Depending on your genotype, the virus is decreased and cannot be measured in 5 to 8 out of every 10 people who take PEGASYS and COPEGUS combination therapy for 6 months to 1 year. After 3 to 6 months of therapy, a blood test can help your healthcare professional determine your likelihood of long-term response.

COPEGUS is taken in the form of several pills every day in addition to PEGASYS therapy. Since all medications can cause side effects, it's possible that you could experience side effects while taking COPEGUS and/or PEGASYS. If you have any questions about your treatment options, be sure to speak with your healthcare professional.

Roche Patient Assistance Program



Pegassist is a comprehensive patient education and support program. It provides important information about hepatitis C, treatment options, and tips for daily living when you have hepatitis C. The services offered here on Pegassist.com are just part of the total Pegassist program.

To sign up for additional Pegassist features, all you have to do is call our toll-free number: **1-877-PEGASYS (1-877-734-2797)**.

INTERMUNE®



Infergen® (Interferon alfacon-1), also known as consensus interferon, is a recombinant, bio-optimized, non-naturally occurring type-1 interferon.

Infergen is indicated for the treatment of chronic hepatitis C virus (HCV) infection in patients 18 years of age or older with compensated liver disease. Patients who tolerated previous interferon therapy and did not respond or relapsed following its discontinuation may also be subsequently treated with Infergen.

Intermune Patient Assistance Program

InterMune, Inc. is committed to providing services that make access to INFERGEN® as simple and easy as possible. As part of this commitment, the INFERGEN Access Hotline offers physicians, office staff, and patients access to reimbursement specialists who can verify benefits and answer important questions about INFERGEN.

The Hotline also provides patient support services, including telephone access to nurses and pharmacists, and prescription services that include overnight shipping of medication to physicians or patients at no additional cost.

INFERGEN Access Hotline: **1-888-668-3393 (toll-free)**

Hours: Monday - Friday, 9 AM - 8 PM EST

Fax: 1-800-724-8036